AUG 2 4 2000

K002324
p.1 of 2

510(k) SUMMARY

Manufacturer: Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, TX 78717
Tel: (512) 432-9900
Fax: (512) 432-9291

Contact: Frances E. Harrison
Senior Regulatory Affairs Specialist

Classification Name: Knee joint femorortibial metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3510)

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.353)

Common/Usual Name: Hinge Knee for Total Knee Replacement/Hip Stem for Total Hip Replacment/Total Hip and Knee Replacement

Trade/Proprietary Name: Modular Options for Severe bone loss and Trauma (MOST) System

Product Description:

The (MOST) System will be used for the replacement of the proximal, distal or total femur. Replacement of the distal femur would also include replacement of the proximal tibia and the possible resurfacing of the patella, if necessary. Unlike primary hip and knee systems, this system will be used where the amount of femoral resection and restoration required is extreme (e.g., in oncology cases). The modularity of this system allows for the resection of varying amounts of the femur (and the proximal tibia and patella, if necessary) before implantation. A total replacement is possible in those cases where no part of the femur can be salvaged. The components of the MOST System include:

- The proximal femoral replacement is available in two designs to address the presence or absence of the greater trochanter, with suture holes for soft tissue attachment;
- The distal femoral replacement which mates with a tibial component via a hinge-type mechanism, allowing 15 degrees of internal and external rotation;
- Intramedullary (I/M) stems with Cancellous Structured Titanium™ (CSTi™) and femoral segments which will be used in conjunction with the proximal and distal replacements,
- Two options of a condylar end: A standard condylar end which is intended for use with I/M stems or Most segments and a bone-conserving condylar end which is intended for use with the Natural-Knee II revision stems.
- An all-poly patella.

K002324
P. 2.82

Intended Use/Indications for Use:

The MOST System is intended to replace the proximal, distal or total femur, especially in cases that require extensive resection and restoration. Replacement of the distal femur would also include replacement of the proximal tibia and the possible resurfacing of the patella, if necessary. Proximal replacement components are available for press-fit or cemented use. Components used for replacement of the distal femur are for cemented use only. Specific indications for use of the MOST System include:

- Metastatic diseases (e.g., osteosarcomas, chondrosacromas, giant cell tunors, bone tumors) requiring extensive resection(s) and replacement(s) of the proximal/distal femur.

- Revision cases requiring extensive resection(s) and replacement(s) of the proximal/distal femur.

- Severe conditions of inflammatory or non-inflammatory degenerative joint disease requiring extensive resection(s) and replacement(s) of the proximal/distal femur.

Substantial Equivalence:

The MOST System is substantially equivalent to products offered by Wright Medical Technology, Inc., Waldermar Link, Joint Medical Products Corporation and Howmedica, Inc. The Segmented Oncology System (S.O.S.™) Proximal Femur (Wright Medical) and the MP Reconstruction Prosthesis (Link) are both modular stem designs which allow for necessary length adjustment. This provides surgeon's with intraoperative flexibility in a variety of clinical situations.

The Hinge-Type Knee of the MOST System is substantially equivalent to the Noiles Total Knee Prosthesis (Joint Medical Products Corporation) and the Kinematic II Rotating Hinge (Howmedica).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2000

Ms. Frances E. Harrison
Senior Regulatory Affairs Specialist
Sulzer Orthopedics Inc
9900 Spectrum Drive
Austin, Texas 78717

Re: K002324
Trade Name: Modular Options for Severe bone loss and trauma (MOST™ System)
Regulatory Class: II
Product Code: JDI, KRO, and LZO
Dated: July 28, 2000
Received: July 31, 2000

Dear Ms. Harrison:

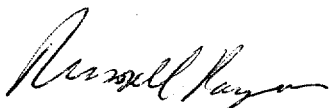
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002324

Device Name: **Modular Options for Severe bone loss and Trauma (MOST) System**

Indications For Use:

The MOST System is intended to replace the proximal, distal or total femur, especially in cases that require extensive resection and restoration. Replacement of the distal femur would also include replacement of the proximal tibia and the possible resurfacing of the patella, if necessary. Proximal replacement components are available for press-fit or cemented use. Components used for replacement of the distal femur are for cemented use only. Specific indications for use of the MOST System include:

1. Metastatic diseases (e.g., osteosarcomas, chondrosacromas, giant cell tunors, bone tumors) requiring extensive resection(s) and replacement(s) of the proximal/distal femur.

2. Revision cases requiring extensive resection(s) and replacement(s) of the proximal/distal femur.

3. Severe conditions of inflammatory or non-inflammatory degenerative joint disease requiring extensive resection(s) and replacement(s) of the proximal/distal femur.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002324

Prescription Use X **OR** **Over-The-Counter Use** _____

(Optional Format 1-2-96)